

Treatment of carpal tunnel syndrome with eswt: A sham controlled double blinded randomised study

Treatment of carpal tunnel syndrome with shock wave

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Abstract

Aim: The aim of this study was to investigate the efficiency of extracorporeal shockwave therapy (ESWT) in the treatment of Carpal tunnel syndrome (CTS). **Material and Method:** In the study 49 hand with the diagnosis of CTS were included. Patients were randomized in ESWT (n=29 hands) and sham (n=20 hands) groups. Patients were randomly allocated to receive 1 session per week for 3 weeks of either sham or active ESWT. Patients were evaluated before the treatment, and at the end of the first week, first month and third month after the end of the treatment session with Boston Scale, Visual Analogue Scale for pain and paresthesia assessment, hand grip strength, and electroneurophysiological parameters. **Results:** A total of 38 patients completed the study with 29 wrists in active ESWT and 20 wrists in sham ESWT groups. Groups were similar in age, sex, duration of symptoms, hand grip strength, and electrodiagnostic parameters ($P>0.05$). In both groups, significant improvements were observed in VAS, Boston Scale, and hand grip strength after treatment. In both groups, there was no significant difference in none of the clinical and electrodiagnostic parameters ($p>0.05$). **Discussion:** Although ESWT was effective in symptoms in CTS this efficacy isn't superior to placebo. Our results indicated that ESWT was effective in pain and clinical variables in CTS. Wider and high-quality studies are needed to further demonstrate the effectiveness of ESWT in the treatment of CTS.

Keywords

Carpal Tunnel; Splint; Shock Wave; Pain; Paresthesia; Conservative Treatment

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Introduction

Carpal tunnel syndrome (CTS) is the most common form of entrapment neuropathy, resulting from median nerve compression within the carpal canal [1]. Main symptoms are tingling, pain and a numb feeling in the first three fingers and the radial side of the fourth finger. Symptoms are aggravated in the evening. Due to the median nerve has more sympathetic fiber, symptoms widespread throughout the shoulder [2]. The motor disturbance which can range from the weakness of the thenar muscles innervated by the median nerve through to complete paralysis and atrophy [3]. Impairments in palmar thumb abduction and opposition strength. Diagnosis is based on clinical history and examination findings with electrophysiological diagnostic tests [4].

Treatment options for CTS may be surgical or nonsurgical. Nonsurgical treatment is used for patients with mild and moderate cases. There are many methods for nonsurgical treatment and none of them was found superior to the others which include wrist splint, local corticosteroid injections, nonsteroidal anti-inflammatory drugs (NSAID), vitamin B6, diuretics, alfa-lipoic acids, tendon gliding exercises, physical therapy agents (ultrasound, TENS, laser, paraffin, iontophoresis etc.) [5,6,7]. In severe cases, surgery is considered the treatment of choice. In recent years, extracorporeal shock wave therapy (ESWT) has been used in musculoskeletal disorders [8].

The shockwave generated is a sonic pulse and is characterized by an initial rise, reaching a positive peak of up to 100 MPa within 10 ns, followed by a negative amplitude of up to -10 MPa and a total life cycle of less than 10 μ s. The maximal beneficial pulse energy must be concentrated at the point at which treatment is to be provided. There are two basic effects: generation of mechanical forces and anti-inflammatory effects on soft tissue [9]. Only a few studies evaluated the efficiency of ESWT for CTS treatment. Only one study reported prospective, randomized, double-blind, placebo-controlled. The aim of this study was to investigate clinical and electrophysiological findings after ESWT treatment in CTS compared to the control group.

Material and Methods

This study was designed as a randomized, placebo-controlled, double-blind clinical trial on patients with CTS during 2014–2015. All patients were informed about the content, purpose, and application of the study and their approvals were obtained. The study protocol was approved by the local Ethics Committee. Patients aged between 18 and 65 years who consulted to our clinic with at least 3 months of complaints were evaluated to be included. The diagnoses of all cases were ensured by nerve conduction studies. For the diagnosis of CTS, prolongation in median nerve distal motor latency and/or distal sensory peak latency, reduction of distal sensory transmission velocity, low distal latency of median sensory nerve action potential (SNAP) and distal latency of median compound muscle action potential (CMAP) amplitudes was considered significant. In addition, based on Stevens criteria, patients were classified as mild, moderate and severe according to the severity of electrophysiological findings [10]. Patients who were diagnosed with mild to moderate CTS were included in the study.

Clinical examinations were performed on the patients included in the study prior to the treatment and the data obtained were recorded with the electrophysiological findings and the evaluation forms were filled out. Demographic information such as

age, gender, body mass index (BMI), hand dominance, symptomatic hand (dominant, non-dominant, bilateral), hand under study (dominant, non-dominant), duration since the beginning of symptoms (months), CTS symptoms, any other existing diseases, if applicable history of surgery and trauma were recorded and physical examinations were performed for all individuals included in the study. Both hands were included in the study, provided that they met the criteria, in patients with bilateral symptomatic CTS. An ESWT device of Gymna brand, shockmaster 500 model (storz medical, Tagerwilan, Switzerland) was used. Patients were divided into two groups by simple randomization and while one group received ESWT at a therapeutic dose (0.10 mJ / mm²), the control group (Sham) has taken an ineffective dose (0.01 mJ / mm²) of ESWT. Both groups were given hand-wrist resting splints as a base treatment. Prior to the study, the patients were randomized active ESWT and sham ESWT groups. ESWT was administered to the patients in the active groups in 3 sessions per week for 3 weeks, at a therapeutic dose (0.10 mJ / mm²) to the wrist in a way to amount 1500 shots per session. ESWT applications to active and sham groups were performed by the same individual with soundproof headphones and snow gloves.

The same treatment protocol was implemented for the patients in the sham group. However, the bullet on the ESWT device header was removed by the individual making randomization, and thus, enabled the device to operate at an inactive dose (0.01 mJ / mm²). No acoustic shock waves were produced as there was no bullet inside the device header. The screen of the ESWT device was closed with an opaque paper again by the randomizing person to prevent the practitioner from seeing the screen.

Since the operating sound and vibration characteristics of the device alter when the bullet is removed, the practitioner used gloves to minimize the feeling of vibration and sound-proof headphones in both administrations so as not be aware of which group is being treated. Patients who had been previously treated with ESWT in any part of the body were not included in the study to ensure patient blindness. Patients in both groups were given a volar supported static hand-wrist splint that holds wrists in the neutral position, to be used for 12 weeks at nights only. During this time period, patients were not permitted to use another analgesic medication (only paracetamol).

Patients were evaluated before and after the treatment, in the 1st week, at the 1st and 3rd months. To evaluate pain and paresthesias, patients were asked to mark a point on a 10-cm visual analog scale (VAS), rated from 0 to 10. Boston Carpal Tunnel Questionnaire (BCTQ): The symptom severity subscale consists of 11 questions with scores from 1 point to 5 points (most severe), and the functional status subscale is made up of 8 questions with scores from 1 point (no difficulty in activity) to 5 points (unable to perform the activity at all). The mean scores are obtained by the division of the total score by the number of questions. In this study, mean scores were utilized. Hand grip strength was assessed by the North Coast TM Jamar hand dynamometer. Electrophysiological evaluation at the 3rd month. Descriptive statistics are presented as frequency, percentage, mean, standard deviation (SD), median, minimum (min), and maximum (max) values. Fisher exact test or Pearson's chi-square test was utilized for the analysis of the relationships between categorical variables. In the normality test, the Shapiro-Wilks test has been used when the number of samples in the group was smaller than 50 and Kolmogorov-Smirnov test was utilized

when the number of samples was bigger. In the analysis of the differences between measurement levels of the two groups, the Mann-Whitney U test has been used if the distribution did not fit to a normal one and the Student's t-test has been performed when it followed a normal distribution. In the analysis of time changes for each group, the Friedman test has been used when the measurements did not comply with the normal distribution. When the differences between the measurements were significant, the Bonferroni-Dunn test has been used in paired comparisons. The analyses were done via the use of SPSS 21.0 package program. P values less than 0.05 were considered to be statistically significant.

Results

The study enrolled 43 patients but five of them were excluded because of dropout. A total of 49 wrists were included in the study. In unilateral CTS group, there were 27 patients and 11 patients were in bilateral CTS group. After randomization, 29 wrists were treated with ESWT and 20 wrists were treated with sham ESWT therapy. Patients completed a three-week treatment protocol and three months follow-up period. No adverse effects were recorded during the study. The baseline demographic properties, clinical characteristics (Table-1) and treatments parameters (Table-2) were similar between the two groups ($p>0.05$). VAS pain-paresthesias, BCTQ scores, electrophysiological results and hand grasp strength before and after treatment were presented in Figure-1, Figure-2, Figure-3, Table-3 respectively. The VAS and BCTQ scores and hand grasp measurements in both groups showed significant improvement at all follow-up time points, compared with baseline measures (all $P<0.05$); not including the first-week hand grasp of the control group [$P>0.05$]). For the electrophysiological results, there was no significant change at all follow-up time points, compared with baseline ($P>0.05$) (except for BKAP amplitude value at weeks 12 in the ESWT group). There was no significant difference between the two groups in all parameters.

Discussion

CTS is one of the most common occupational diseases that

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants

	ESWT Group (n=29)	Sham Group (n=20)	P Value
Sex			1.000
Male(n)(%)	2 (%7)	2 (%10)	
Female(n)(%)	27 (%93)	18 (%90)	
Age (year) (Mean±SD)	51.28±9.16	51.65±7.37	0.880
Dominant hand			1.000
Right(n)(%)	26 (%90)	18 (%90)	
Left(n)(%)	3 (%10)	2 (%10)	
Lesion site			1.000
Right side(n)(%)	13 (%45)	9 (%45)	
Left side(n)(%)	18 (%55)	11 (%55)	
Pain (yes/no)	21/8	16/4	0.738
Paresthesias (yes/no)	29	19/1	0.408
Phalen (positive/negative)	24/5	17/3	1.000
Tinel test (positive/negative)	17/12	13/7	0.652
Carpal Compression (positive/negative)	12/17	5/15	0.236

Table 2. Pre-Treatments Parameters of the Study Participants

	ESWT Group (n=29)	Sham Group (n=20)	P Value
Visual analog scale			
pain (cm)	4.68±3.41	3.75±3.00	0.253
paresthesias (cm)	6.86±1.87	6±2.02	0.087
Boston Carpal Tunnel Syndrome Questionnaire score			
Severity	2.39±0.69	2.3±0.73	0.608
Function	2.23±0.57	1.8±0.69	0.033
Sensory nerve conduction velocity (m/s)	38.57±5.41	39.9±5.27	0.400
Distal motor latency (ms)	4.31±1.07	4.25±1.16	0.817
Compound muscle action potential Amplitude (µV)	22.34±14.96	25.15±12.27	0.254
Hand Grasp (kg)	19.1±9.69	22.8±0.69	0.073

Table 3. Comparison of the electrophysiological before treatment and 3 months after treatment by the two groups.

		ESWT (n=29)	Sham (n=20)	P
SNVC(m/sn)	baseline	38,57±5.41	39,90±5.27	0,400
SNVC(m/sn)	3.month	40,11±7,21	42,77±6,19	0,134
Distal Motor latency (ms)	baseline	4,31±1,07	4,25±1,16	0,817
Distal Motor latency (ms)	3.month	4,33±1,17	3,94±0,87	0,247
CMAP amplitude (µV)	baseline	22,34±14,96	25,15±12,27	0,254
CMAP amplitude (µV)	3.month	25,96±14,63	27,33±8,02	0,618
SNAP (ms)	baseline	4,19±0,62	4,22±0,56	0,855
SNAP (ms)	3.month	4,07±0,91	3,94±0,53	0,774

can lead to functional losses as well as loss of labor force. However, the debate on the effectiveness of conservative approaches utilized in the treatment of CTS and the search for new treatment options continues [5]. Therefore, in this study, we designed a double-blind, prospective, placebo-controlled research aiming to investigate the clinical and electrophysiological efficacy of ESWT which has started to be used in the conservative treatment of CTS in the last years. The results of our study indicate the efficacy of ESWT for relieving symptoms of CTS, however, there is no evidence with respect to the added benefits of the treatment when the results were compared to sham therapy. There were no significant changes in any of the electroneurographic parameters in the two groups as compared to pre-treatment values (except for BKAP amplitude value at 12th week in the ESWT group). The main objectives of the conservative treatment methods applied in CTS are to reduce the pressure within the carpal tunnel, relieve symptoms, educate the patient, and increase hand functions in daily activities [11]. ESWT is widely used in the treatment of soft tissue disorders. In 2002, the International Society for Medical Shockwave Treatment (ISMST) has identified the indications of the shock-wave treatment in orthopedic disorders. ESWT is reported to be effective in the healing of calcific rotator cuff tendinitis, epicondylitis, delayed fracture healing and chronic plantar fasciitis [12]. Recently, it has been shown that low-energy ESWT induces an improved rate of functional recovery in the initial phase of regeneration in the aftermath of injuries at the myelinated axons [13,14]. The non-specific inflammatory reactions, which occur after injuries or are caused by microtraumas of similar shockwaves, start at the first seconds and hours. In principal researches on ESWT, it has been observed that proinflamma-

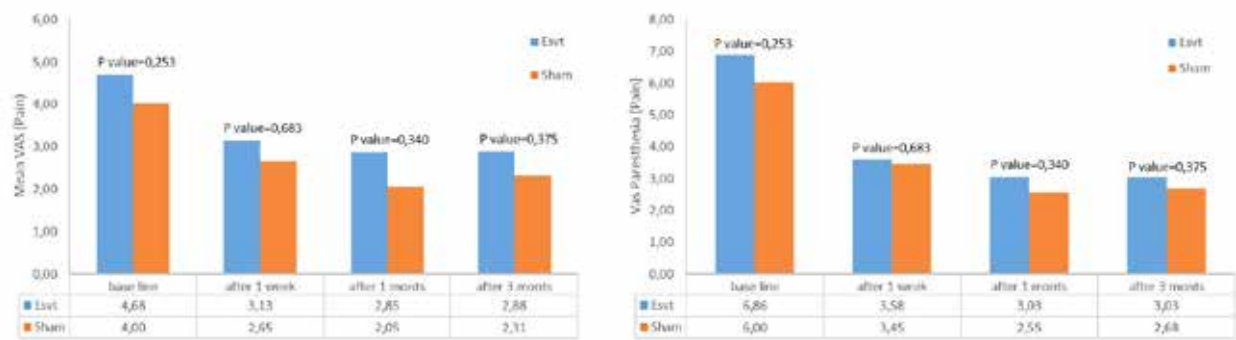


Figure 1 Mean change from baseline in Visual Analog Scale (VAS pain-paresthesia) in all groups in patients with CTS
All $p < 0.001$ between baseline and after 1 week; between baseline and after 1 month and between baseline and after 3 months for both groups

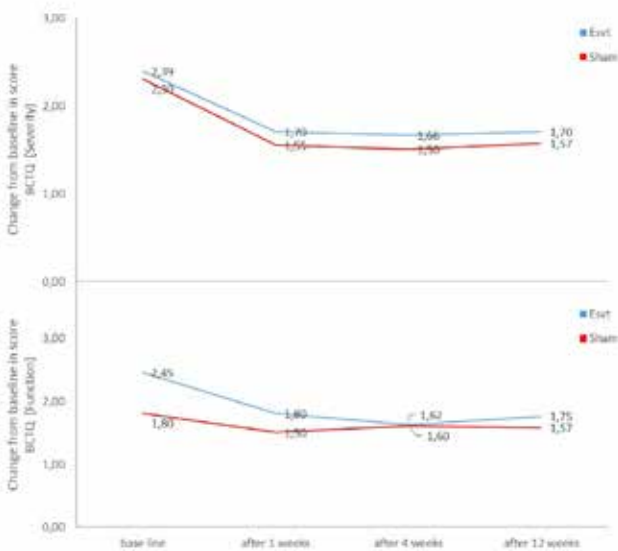


Figure 2 Mean change from baseline in Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) in all groups in patients
All $p < 0.001$ between baseline and after 1 week; between baseline and after 1 month and between baseline and after 3 months for both groups

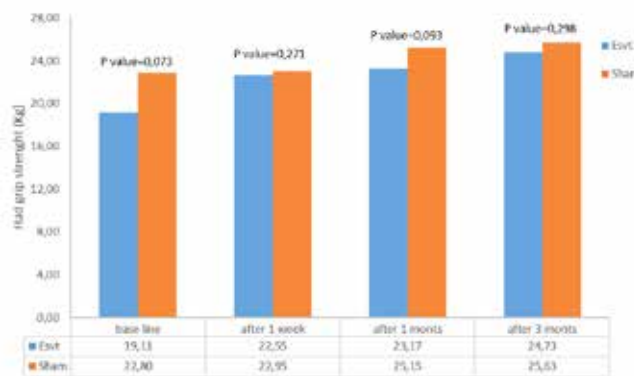


Figure 3 Comparison of the mean score of Hand grip strength in two groups before treatment and after 1 week, 1 month and 3 months
All $p < 0.001$ between baseline and after 1 week; between baseline and after 1 month and between baseline and after 3 months for both groups

tory neuropeptides (substance P and CGRP) are released in the early phases [13]. Besides, it has also been asserted that re-inversion ability of pain receptors and the number of C-fibers, that transmit the pain, decrease after shockwave administration [14,15].

Hauseur T et al. has revealed fewer fibroblasts and less endoneurial collagen in the regenerating nerves in their study of electron microscopic analysis [14]. Improved regeneration of the injured nerves after the ESWT may be considered as a result lower degree of endoneurial scarring due to different fibrocystic

activity in animals. The spinal cord and peripheral nervous system structure in rats and in humans exhibit considerable similarities, but in our study, following the ESWT treatment, only mild but not significant improvement has been observed in the NCS parameters.

Seok H et al. in their study, compared steroid injection and ESWT in 31 patients with CTS [16]. They randomly divided the patients into two groups and administered the ESWT group with 1000 shots at a rate of 360 shots/minute in a single session at the highest tolerable energy density between 0.09-0.29 mJ / mm². In the injection group, they applied 40 mg triamcinolone in the carpal tunnel via USG and followed the patients for 3 months. VAS values of both groups were significantly decreased in the 1st and 3rd months after the treatment. A statistically significant decrease in Boston symptom severity and functional capacity scales was found only in the 3rd month for the injection group and in the 1st and 3rd months for the ESWT group. In the ESWT group, there were no statistically significant differences in the electrophysiological variables between the evaluations before and after the treatment. However, in this study, the ESWT doses were adjusted according to the tolerance level of patients and no standard dose was applied to each patient.

In another prospective, randomized study in which the efficacies of ultrasound and ESWT in terms of treating mild and moderate CTS were compared, 25 patients (45 hands) were randomly divided into 3 groups [17]. All patients were prescribed with neutral positioned resting splints to be used at night and in addition to this, first group was given ultrasound (1 MHz, at a dose of 1.0 Watt / cm², for 3 weeks, 5 days per week, 15 minutes per day), the second group was treated with cryo-ultrasound (on a zero-order skin, at a dose of 1.0 Watt / cm², 1 MHz, for 3 weeks, 5 days per week, 15 minutes per day) and third group was administered ESWT (2500 shots, at an energy intensity of 0,05 mJ / mm², 1 session per week at a total of 4 sessions). Evaluations were made before and at the end of the treatment as well as at the 1st and 3rd months after it. At the end of the treatment and in the controls, a statistically significant improvement for all three groups has been detected in VAS-pain, VAS-paresthesia, BCTQ severity, and BCTQ functional values. The comparison among the groups has shown that the improvement in the BCTQ severity value after the treatment was statistically higher in the ESWT group compared to the others. However, no significant differences were found amongst all three groups in terms of other parameters. There was no control group in this study. No comparisons have been made with the groups that were not administered ESWT and instead of objective parameters (such as hand grip strength or EMG), only subjective parameters (like pain or numbness) have been used for the assessment of treatments.

In the literature, there is only one placebo-controlled, double-blind, and a randomized study investigating the efficacy of ESWT in treating CTS. Wu Yung-Tsan et al. included 34 hands [18]. The patients were randomized into two at a 1: 1 ratio as ESWT and sham groups. All patients included in the study were given a resting splint with a neutral position and ESWT group, along with ultrasonography, was administered ESWT treatments of 3 weekly sessions at a dose of 4 bar pressure, 5 Hz and 2000 shots. The sham group received ESWT with no energy density besides the splint. Subjective assessments were evaluated by using VAS and BCTQ; objective evaluations were conducted with median nerve cross-sectional area, thumb squeezing force (kg) and EMG. Patients were re-evaluated in 1 week, 1 month, 2 months and 3 months after the end of treatment. They have found a significant improvement in both subjective clinical evaluations (VAS, BCTQ) and objective evaluations (median nerve cross-sectional area, thumb squeezing and electrophysiological parameters) in the two groups after the treatment as compared to their pre-treatment conditions. They have also determined that improvement in the VAS, BCTQ values was statistically more significant in the ESWT group than the sham group. In a similar vein to our study, no statistically significant differences have been detected between the two groups in terms of objective evaluations such as electroph, median nerve cross-sectional area and thumb squeezing force. In our study, since the operating sound and vibration characteristics of the device change when the bullet/projectile is removed, we used sound-proof headphones and gloves minimizing the feeling of vibration during all of the applications to ensure that the administrator would not be aware which group was treated. On the other hand, the lack of use of headphones and gloves in Wu Yung-Tsan's study increases the likelihood of partiality as it reduces the blindness of the practitioner. We have found that ESWT was effective on subjective clinical parameters in our study, but this efficacy was not superior to placebo. However, Wu Yung-Tsan et al. has detected in their study that ESWT showed statistically significant superiority to placebo [18]. In this study, high energy (0.40 mJ / mm²) density was utilized. In our study, we used a low energy (0.10 mJ / mm²) density which is commonly utilized in musculoskeletal diseases. The reasons for these conflicting results might be emanating from high energy density usage of ESWT and also from the administration of ESWT along with ultrasonography. The ESWT energy density used in our study may remain ineffective in terms of nerve healing. Nevertheless, Wu Yung-Tsan et al., similar to our study, have not detected any superiority of ESWT over placebo in terms of neural transmission velocity. The similarity results of two studies in terms of clinical objective evaluations suggest that the healing effect of ESWT on nerve regeneration is insufficient. The most important limitations of our study are the small number of patients it has been conducted upon, the short time period for monitoring and the inclusion of non-dominant hands of patients besides the dominant ones.

In conclusion, in this randomized, controlled, double-blind study, it has been determined that the ESWT treatment was not superior to placebo in mild to moderate idiopathic CTS. The use of the hand-wrist resting splint, which is given as the base treatment to all patients included in the study, seems to be effective in reducing the subjective symptoms of CTS. However, these results reflect a short period of time limited to 3 months. Conducting studies examining the effectiveness of the treatment method with a bigger number of patients and over a longer

duration of time would shed light on the contradictions over the subject.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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